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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,250	05/13/2005	Derek O'Hagan	PP18521.004	7392
27476 7590 10/10/2007 NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY R338 P.O. BOX 8097 Emeryville, CA 94662-8097			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT 1648	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/505,250	<b>Applicant(s)</b> O'HAGAN ET AL.	
	<b>Examiner</b> Zachariah Lucas	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 14-19, 21-32 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 20 and 35 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/6/05 and 8/16/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-35 are pending in the application.

#### ***Election/Restrictions***

2. Applicant's election of Group I, and the species indicated on page 7 of the Response filed on August 10, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 14-19, 21-32, and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species or inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 10, 2007.

4. Claims 1-13, 20, 33, and 35 are under consideration.

#### ***Priority***

5. It is suggested that the related applications paragraph on page 1 of the specification be updated to indicate that the present application is a 371 of PCT/US03/05017, filed February 20, 2003, which claims priority to the already identified provisional application.

#### ***Information Disclosure Statement***

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6. The information disclosure statements (IDS) submitted on July 6, 2005 and August 16, 2007 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Soriano et al. (reference C12 in the July 2005 IDS). These claims are drawn to a microparticle composition comprising (a) microparticles comprising a poly( $\alpha$ -hydroxy acid) (especially poly(D,L-lactide-co-glycolide)- PLG), and (b) a polypeptide containing antigen adsorbed to thereto.

Soriano teaches a method for the making of PLG microparticles containing an antigen in the absence of a surfactant. Abstract, and page 551. It is noted that while the reference teaches that the antigen is encapsulated by the microparticles disclosed therein, the teachings of the present application indicate that the protein antigen of the reference would adsorb to the surface of the resulting particles, as well as being encapsulated thereby, in the methods for making the particles disclosed by the reference. It is noted that the reference indicates on page 555 that the lactide/glycolide ratio was 75/25 with a molecular weight of under 40,000. See also, page 557

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(disclosing another embodiment falling within the scope of claim 5). Thus, the teachings of the reference inherently teach the claimed invention.

9. Claims 1-7, 10-12, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Hagan et al (WO 94/27718). Claims 1-5, 7, and 10 have been described above. Claim 6 provides a further identification of the PLG formulation to be used in the microparticle. Claims 11 and 12 require that the composition additionally comprises an antigen. Claim 35 provides a preferred weight: weight ratio of antigen to polymer.

O'Hagan teaches a method for the production of microparticles comprising the use of solvents. Pages 3-4. Detergents are not used in the disclosed methods. The reference teaches that the ratio of lactide to glycolide polymers, and the weights thereof, may be optimized according to the ranges provided in claims 5 and 6 (page 11); and that the ratio of the encapsulated peptide to the polymer may also be optimized (page 16). Thus, the limitations of claims 5, 6, and 35 are obvious as achieved through routine optimization of the indicated microparticle characteristics. The reference also teaches that the microparticles may be used for the encapsulation of antigens, and in such cases may be formulated in compositions additionally comprising an adjuvant. Page 17, lines 13-15. As with the Soriano reference above, the O'Hagan reference does not explicitly teach microparticles with antigen adsorbed thereto. However, the teachings of the present application indicate that the protein antigen of the reference would adsorb to the surface of the resulting particles, as well as being encapsulated thereby, in the methods for making the particles disclosed by the reference. The reference therefore anticipates the indicated claims.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan as applied to claims 1-7, 10-12, and 35 above, and further in view of Krieg et al. (U.S. 6,207,646). This claim describes the microparticle compositions above, wherein the composition comprises a CpG oligonucleotide as an adjuvant. As indicated above, O'Hagan teaches microparticle compositions additionally comprising an adjuvant. However, the reference does not teach or suggest the use of a CpG oligonucleotide as such an adjuvant.

Krieg teaches the use of CpG oligonucleotides as immunostimulants. The reference specifically teaches that such oligonucleotides may be administered as an adjuvant in conjunction with a vaccine. Column 33, lines 28-37. From these teachings, it would have been obvious to those of ordinary skill in the art that these CpG oligonucleotides could be used as the adjuvant suggested by the teachings of O'Hagan. The combined teachings of these references therefore render the claimed invention obvious.

12. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan as applied to claims 1-7, 10-12, and 35 above, and further in view of Pizza et al., (Science 287:1816-20) and in light of WO 2004/032958. Claims 1-7, 10-12, and 35, and the teachings of

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O'Hagan, have been described above. Claims 8 and 9 further require that the antigen is a meningitis antigen, esp. the meningitis protein 287. This antigen is not disclosed by O'Hagan.

However, a protein identified as GNA2132 is disclosed as inducing anti-meningitis bactericidal activity in the Pizza reference. Further, the GNA2132 antigen is identified as being meningitis protein 287 on page 6 of the cited WO reference. In view of these teachings, it would have been obvious to those of ordinary skill in the art to use this antigen in the microparticles of O'Hagan in embodiments wherein the microparticle is being used to induce an anti-meningitis immune response. The combined teachings of these references therefore render the claimed invention obvious.

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hagan as applied to claims 1-7, 10-12, and 35 above, and further in view of Constantino et al. (Vaccine 17:1251-63). Claims 1-7, 10-12, and 35, and the teachings of O'Hagan, have been described above. Claim 20 reads on an embodiment wherein the antigen is a polysaccharide conjugated to a polypeptide. O'Hagan does not disclose such an antigen.

However, such antigens were known to those of ordinary skill in the art. See e.g., Constantino. Because O'Hagan indicates that the microparticles disclosed therein may be used for "a wide variety of antigens" (page 15), it would have been obvious to those of ordinary skill in the art to have used the antigens of Constantino in the particles of O'Hagan for the induction of an anti-*N. meningitidis* immune response. The combined teachings of these references therefore render the claimed invention obvious.

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14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### *Conclusion*

15. No claims are allowed. Claim 33 is objected to for depending from a withdrawn claim.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/

Patent Examiner, AU 1648